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APPLICATION NUMBER: *60/484,711*
FILING DATE: *July 03, 2003*
RELATED PCT APPLICATION NUMBER: *PCT/US04/21521*

Certified by

Jon W Dudas

Acting Under Secretary of Commerce
for Intellectual Property
and Acting Director of the U.S.
Patent and Trademark Office

Express Mail No. EV238420586US

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 C.F.R. 1.53 (c).

Docket Number	COR21 PP306

INVENTOR(s)/APPLICANT(s)			
LAST NAME	FIRST NAME	MIDDLE INITIAL	RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)
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TITLE OF THE INVENTION (280 characters max)

WOUND DRESSING, INGREDIENT DELIVERY DEVICE AND IV HOLD DOWN, AND METHOD RELATING TO SAME

CORRESPONDENCE ADDRESS

Customer No. 000,277

STATE		ZIP CODE		COUNTRY	

ENCLOSED APPLICATION PARTS (*check all that apply*)

X Specification *Number of Pages* 14 — Small Entity Statement

X Drawings *Number of Sheets* 4 — X Other (specify) X Return Postcard

METHOD OF PAYMENT (*check one*)

x	A check or money order is enclosed to cover the Provisional filing fees	PROVISIONAL FILING FEE AMOUNT ($160.00)	
x	The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number: 16-2463		

The Invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

James A. Mitchell

James A. Mitchell Reg. No. 25 120 Date July 3, 2003

☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

Attorney Docket No. COR21 PP306
Express Mail No. EV238420586US

WOUND DRESSING, INGREDIENT DELIVERY DEVICE AND IV HOLD DOWN, AND METHOD RELATING TO SAME

BACKGROUND OF THE INVENTION

The present invention relates to adhesive devices used as wound dressings, ingredient delivery devices and IV hold downs.

Wound dressing and IV hold downs in particular comprise a layer of polymeric film having an adhesive layer on one side thereof, which is protected during storage and handling by a release liner. United States Patent Publication 2002/0107466 A1 discloses such devices which also have a handling member adhered to the non-adhesive coated side of the polymeric film by means of a pressure sensitive adhesive. The pressure sensitive adhesive used between the handle and the polymeric film is less aggressive than the pressure sensitive adhesive used on the underside of the polymeric film, such that once the polymeric film is applied to a patient's skin or mucosa, the handle can be peeled away without peeling the polymeric film away from the patient's skin.

Experience has shown that regardless of differences in adhesive strength between the skin or mucosa adhesive and the handle adhesive, there is a tendency for the edge of the polymeric film to lift away from the user's skin or mucosa when the handle member is peeled away from the back of the polymeric film. This same tendency is observed in the wound dressing disclosed in U.S. Patent 6,169,224, where the handling member is sealed to the polymeric film by a heat activated adhesive.

SUMMARY OF THE INVENTION

It has been surprisingly discovered that inadvertent edge release caused by peeling the handle member away from the polymeric film can be minimized by minimizing the electrostatic

charge buildup in the localized area of the polymeric film beneath the handle, as the handle is peeled away from the film. In various different preferred aspects of the invention, this is accomplished by:

1. interrupting the continuity of contact between the adhesive coated surface of the handle and the underlying non-adhesively coated surface of the polymeric film; and

2. placing an anti-static ingredient in one of, the adhesive coating on the underside of the polymeric film, or in an anti-static coating on the upper or lower surface of the polymeric film itself, with the anti-static agent preferably being located in the adhesive layer on the underside of the polymeric film.

In another aspect of the invention, an inwardly-directed thumb tab, oriented at an obtuse angle with respect to the edge of the handle in the direction in which the handle is pulled, is provided to facilitate peeling of the handle away from the polymeric film. Such a thumb tab enhances the ease with which the handle is peeled away from the polymeric film. The thumb tab starts the peeling at such an angle that the tendency of the handle to lift the underlying polymeric film away from the patient's skin or mucosa is minimized.

These and other objects, features and advantages of the invention will be more fully understood and appreciated by reference to the written specification and appended drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a plan view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a first embodiment of the present invention;

Fig. 2 is a cross sectional view of the wound dressing, ingredient delivery device, or IV hold down of Fig. 1, taken along line II-II;

Fig. 3 is a perspective view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 1, with the handle being removed;

Fig. 4 is an enlarged sectional view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 2, taken along section IV-IV with the release liner removed;

Fig. 5 is a plan view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a second embodiment of the present invention;

Fig. 6 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 5, taken along line VI-VI;

Fig. 7 is a plan view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a third embodiment of the present invention.

Fig. 8 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 7, taken along line VIII-VIII;

Fig. 9 is a plan view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a fourth embodiment of the present invention.

Fig. 10 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 9, taken along line X-X;

Fig. 11 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a fifth embodiment of the present invention;

Fig. 12 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a sixth embodiment of the present invention;

Fig. 13 is a cross sectional view of a wound dressing, ingredient delivery device, or IV hold down in accordance with a seventh embodiment of the present invention;

Fig. 14 is a cross sectional of a wound dressing, ingredient delivery device, or IV hold down in accordance with an eighth embodiment of the present invention; and

Fig. 15 is a plan view of a wound dressing, ingredient delivery device, or IV hold down of Fig. 14.

BACKGROUND OF THE INVENTION

INTRODUCTION

In the preferred embodiment, the basic elements of a device in accordance with the present invention comprise a handle 10 having an adhesive coating 20 on the undersurface thereof and an inwardly-projecting thumb tab 11 (Figs. 1-3). Handle 10 is applied to the nonadhesive coated surface of a polymeric film 30 having a pressure sensitive adhesive layer 40 on the undersurface thereof. Adhesive layer 40 is protected during handling and storage by a release liner 50 having a silicone coating layer 51. In use, release liner 50 is removed from the assembled polymeric film 30 and handle 10, and handle 10 is then used to manipulate the polymeric film and place it on the patient. Once the polymeric film as been applied to the patient, the user grasps inwardly-projecting thumb tab 11 on handle 10 and peels handle 10 away from the applied polymeric film 30.

Inadvertent edge release caused by removal of the handle 10 is minimized by:

1. the angle at which thumb tab 11 projects from handle 10; and
2. by minimizing the build up of localized electrostatic charge on the polyurethane film as the handle is removed.

Minimizing electrostatic buildup is accomplished by:

1. interrupting the continuity of contact between the adhesive coated surface of the handle and the underlying non-adhesively coated surface of the polymeric film; or
2. placing an anti-static ingredient in one of, the adhesive coating on the underside of the polymeric film, or in an anti-static coating on the upper or lower surface of the polymeric film itself, with the anti-static agent preferably being located in the adhesive layer on the underside of the polymeric film.

As depicted in figure 1, handle 10 includes inwardly-projecting thumb tab 11. Handle 10 is preferably made of a stiffer and generally thicker material than that of polymeric film 30. Typical of such materials are plastic or paper material. Useable plastics include polyesters, polycarbonates, PVC's, polyurethanes, polyethylene vinyl acetates, polyester copolymers, polyethylenes, and polypropylenes. In the preferred embodiment a silicone coated paper 50, with a silicone coat 51 on the upper surface thereof, is used.

The entire undersurface of each handle 10 is coated with an adhesive 20, preferably a pressure sensitive adhesive (Fig. 2), which is moderately aggressive with respect to polymeric film 30, but which does not adhere or adheres less aggressively to either the silicone coating 51 on release liner 50 or to human skin. In this way, a user can readily fold back an end portion of release liner 50 to expose an end of handle 10, and the exposed end can then be used to peel film 30 away from release liner 50. The adhesive of layer 20 is "moderately aggressive" in that handle 20 remains attached to polymeric film 30 when it is peeled away from release liner 50, and while it is being handled and applied to the patient's skin. However, adhesive 20 is less aggressive with respect to its adhesion to polymeric film 30, than is the adhesion of layer 40 on

the undersurface of polymeric film 30 toward human skin or mucosa. As a result, handle 10 can be peeled away from polymeric film 30, once film 30 is applied to the patient.

One type of adhesive which we have found useful for layer 20 on the undersurface of handle 10 is a low tack removable acrylate-based adhesive with a peel adhesive level of approximately three ounces. Other useful adhesives include, but are not limited to, silicone, urethane, synthetic rubber and natural rubber. Adhesives of this type can be formulated to have essentially no or very little adhesion to the human skin or to the silicone coating 51 on the release liner 50, but still adhere firmly but releasably to film 30.

Polymeric film 30 is preferably comprised of any breathable and waterproof material. In the preferred embodiment, a polymeric film on the order of from about 0.5 to about 4 mils (0.0005 to 0.004 inches) is preferred. The film is preferably very flexible, allowing it to conform readily to the user's skin or mucosa. The film must have sufficient strength to afford resistance to damage in handling and in use. It also preferably allows the passage of oxygen, thereby allowing the skin or mucosa to breathe. The polymeric film material preferably is a polyurethane film such as a Pebax® film (MediFilm 810, 2 mils, Mylan). Additionally, copolymers of polyethylene and vinyl acetate are also preferable.

The adhesive layer 40 may be any adhesive that bonds well to skin or mucosa. Preferably, a pressure sensitive adhesive is used. A type of adhesive found useful for adhesive layer 40 is a permanent acrylate-based pressure sensitive adhesive designed for skin, with a peel adhesion level of approximately 50 ounces. Other useful adhesives include, but are not limited to, silicone, urethane, synthetic rubber and natural rubber. Such adhesives can be formulated to adhere releasably to the silicone coated surface 51 of a release liner 50. At the same time, they can be formulated to adhere firmly to the patients skin or mucosa such that polymeric film 30

will not peel away unless someone intends to do so. For example, one can use an acrylate derivative adhesive such as copolymers of alkyl acrylate/vinyl acetate containing –OH or/and –COOH functional groups, or hydrophobic styrenic rubber polymer or PIB containing 1 to 20% hydroattractants such as PVP, PVA, and cellulose derivatives such as Duro-Tak 87-2516 (National Starch), and PIB containing 20% Kollidon® CL-M (BASF).

The entire assembly of handle 10, adhesive layer 20, polymeric film 30 and adhesive layer 40 is releasably adhered to a release liner 50. Release liner 50 may be comprised of any material that will releasably adhere adhesive layer 40. However, in the preferred embodiment, release liner 50 is a paper material with a silicone coating 51 on the top surface thereof.

THE ANGLED THUMB TAB

The very properties of polymeric film 30 which make it desirable in use make it difficult to handle in application. The drape and flexibility properties of polymeric film 30 may cause it to fold over onto itself and self-adhere relatively easily when one is trying to apply the system to the user's skin. The handle 10 disclosed in the preferred embodiment reduces these shortcomings and makes the systems relatively easy to apply without fouling polymeric film 30. However, the structural characteristics of the stiffer and generally thicker material of handle 10 which aid in the application is compromised when a cut line 13 is made to handle 10 (Fig. 1). Cut line 13, which aids the applicator in the removal of handle 10, compromises the structural integrity of handle 10 and allows the polymeric film 30 to fold over and adhere to itself. Tab 11 is provided on handle 10 to minimize this tendency as well as aid in the removal of handle 10.

As depicted in figure 1, inwardly-projecting thumb tab 11 is adhered to polymeric film 30 with adhesive coating 20 as described above and includes a distal portion 12. In the preferred embodiment, Tab 11 is disposed at an angle greater than 90 degrees with respect to the edge of

the handle in the direction in which the handle is pulled, and distal portion 12 extends beyond cut line 13 into window 15 of handle 10. Preferably, the angle is between about 120° and about 150°, and most preferably about 135°. This placement of distal portion 12 provides more support for polymeric film 30 and handle 10 and it is therefore less likely that polymeric film 30 will fold at cut line 13. However, this is merely the preferred embodiment and tab 10 may also be disposed outwardly. Similarly, it is preferably that cut line 13 extends between the edges of handle 10 at between about 130° and about 150°, most preferably about 135°, with respect to the direction in which handle 10 will be initially peeled away from film 30. This also helps prevent film 30 from buckling across the cut through the handle.

As described above, edge release typically occurs with these systems when handle 10 is removed from polymeric film layer 30. Tab 11 minimizes this tendency by reducing the mechanical advantage that handle 10 has over polymeric film 30 when handle 10 is being peeled off. The mechanical advantage is reduced by the angle at which thumb tab 11 projects from handle 10 and subsequently, the angle at which handle 10 is removed from polymeric film 30.

INTERRUPTING THE CONTINUITY OF CONTACT BETWEEN THE HANDLE AND THE POLYMERIC FILM

In addition to the mechanical advantages of thumb tab 11, edge release can also be minimized by interrupting the continuity of contact between the adhesive coated surface of the handle and the underlying non-adhesively coated surface of the polymeric film. Although not wishing to be bound by theory, it is believed that this interruption helps to minimize edge release in three ways:

1. less contact area means handle 10 can be removed more easily;

2. at least in some configurations, e.g., the diagonal slots of the Fig. 1 embodiment, the mechanical advantage of the handle relative to the film 30 edge is reduced; and

3. localized electrostatic build up when handle 10 is peeled away from film 30 is reduced.

Interrupting the contact between the adhesive layer 20 of handle 10 and film 30 reduces the contact area. We have found it helpful to reduce the contact area by from about 10% to about 70%, preferably about 10% to about 50%, and most preferably from about 10% to about 30%, as compared to the contact area without such interruptions in continuity. If a greater reduction in contact area is desired, a more aggressive adhesive can be used in adhesive layer 20.

One technique for interrupting the adhesive layer of the handle and the non-adhesively coated surface of polymeric film 30 is to texture handle 10, at least at adhesive layer 20 on handle 10 which faces and is adhered to polymeric film 30. Preferably, this texturing is done by piercing slots 16 through handle 10 and adhesive coating layer 20 (Figs. 1-6). Other techniques include placing pin holes through handle 10 (Figs. 7, 8); knurling handle 10 (Figs. 9, 10); embossing or debossing handle 10; printing adhesive layer 20 in a pattern (Fig. 11); and employing a handle material having a relatively rough surface facing polymeric film layer 30. Alternatively, the polymeric film 30 may be textured on the side facing handle 10 (Fig. 12). Preferably, the texturing is done in such a way as to break the adhesive coating layer itself, as distinguished from merely making it irregular in shape (see e.g., Figs. 2, 4 and 8).

As depicted in Fig. 1, a first embodiment is shown utilizing a plurality of piercing slots 16 completely surrounding and angularly disposed with respect to window 15. The slots 16 may

be pierced from the either side. However, in the preferred embodiment the slots are pierced from the top surface and through adhesive layer 20 on handle 10 as shown in Fig. 2.

A second embodiment is shown in figure 5 using a different pattern of slots. Whereas in the Fig. 1 embodiment, the slots 16 are oriented diagonally between the inner and outer edges of handle 10, in the Fig. 5 embodiment, slots 16a are oriented generally parallel to the inner and outer edges of handle 10a. Comparable features of this and the other embodiments are designated with a letter corresponding to the associated feature number.

In response to the piercing action, material of handle 10 at the pierced location is deflected toward polymeric film layer 30 resulting in a raised portion 17 of slot 16 (Fig. 2). Raised portion 17 effectively reduces the adhesive area and therefore the adhesive retention of handle 10 to polymeric film 30. Film 30 tends to bridge over raised portions 17 of slots 16, creating a "tunnel" at which film 30 is separated from handle 10. When handle 10 is removed from polymeric film 30 an atmospheric venting effect 21 occurs in the tunneling area (Fig. 4). This venting effect enhances the ease of removal of the handle. The reduced adhesion allows tunnels 21 of non adhered polymeric film 30 to be created between handle 10 and polymeric film 30 directly underneath slots 16. This venting effect reduces the adhesion of handle 10 to polymeric film 30 so that, after polymeric film 30 has been applied, when handle 10 is removed, the result is less inadvertent edge release. Additionally, raised portion 17 which is in contact with polymeric film 30 provides a conductive pathway between polymeric film 30 and handle 10. This pathway interrupts the continuity of contact between the adhesive coated surface 20 of handle 10 and the underlying non-adhesively coated surface of polymeric film 30 thereby minimizing the electrostatic buildup of localized electrostatic charge on the polyurethane film

during the removal of handle 10. This minimization of electrostatic build up contributes towards the reduction in edge release.

Figure 5 shows a second embodiment including slots 16a which are parallel to window 15a along its sides, and angularly disposed with respect to the top and bottom surface. In this configuration, after the release liner 50a is removed, atmospheric venting effect 21a again occurs, but to a lesser extent as compared with the first embodiment (Fig. 6). The lessoning of the venting effect can be attributed to the use of fewer slots 16a as well as their parallel configuration. Additionally, film 30 tends to "tent" over individual slot ends 17a, rather than bridging over several adjacent slot ends and forming more of a tunnel.

A third embodiment is shown in figure 7 and is similar to the first two embodiments except that it utilizes a puncture or pinhole to interrupt the continuity between the handle 10b and the polymeric film 30b. As shown in figure 8, pinholes 16b minimize edge release by reducing the adhesion of handle 10b to the polymeric film 30b and also providing a conductive pathway between polymeric film 30 and handle 10 in order to minimize electrostatic buildup as described above.

A fourth embodiment using a knurled pattern is depicted in figure 9. The knurled pattern may take any geometrical shape and be either embossed or debossed on handle 10c. Additionally, the pattern may be varied thereby increasing or decreasing the contact area to accommodate the application requirements. Unique to this embodiment is the feature that the knurls 16c do not puncture handle 10c. Instead, the reduction in adhesion is accomplished through the bottom of knurls 16c residing directly on polymeric film layer 30c and therefore reducing the adhesive contact surface of polymeric film 30c, as shown if figure 10. However, this is not meant to be limiting and knurls 16c may puncture handle 10c if required. Embossing

or debossing handles 10 is similar to knurling, though the raised portion would probably be larger in area than the knurl projections.

Additionally, a fifth embodiment is shown in figure 11. This embodiment reduces the adhesion between handle 10d and polymeric film layer 30d by patterning the adhesive layer. As described above, the pattern may be varied thereby increasing or decreasing the contact area according to the specific requirements of the application.

Still further, it is possible to accomplish this reduction in continuity through the use of a rough surface or handle 10, facing polymeric film layer 30. This can be done, for example, through the use of a rough or non smooth paper for handle 10.

TEXTURING THE POLYMERIC FILM SURFACE WHICH FACES ADHESIVE LAYER 20 ON HANDLE 10

Figure 12 shows a sixth embodiment which uses a polymeric film layer 30e having at least a textured upper surface to reduce the continuity of contact between handle 10e and polymeric film 30e. The pattern may take any geometrical shape and be either embossed or debossed on polymeric film layer 30e. Additionally, as described above, the pattern may be varied thereby increasing or decreasing the contact area to accommodate the application requirements. The patterning of polymeric film layer 30e may be accomplished mechanically or chemically.

INCORPORATING AN ANTI-STATIC INGREDIENT

Edge release can also be minimized by utilizing an anti-static coating to minimize the electrostatic buildup that occurs when handle 10 is removed. A seventh embodiment using an anti-static coating 61 is shown in figure 13. The anti-static coating layer 61 on polymeric film layer 30f acts to minimize the electrostatic buildup of localized electrostatic charge on polyurethane film 30f during the removal of the handle 10f. The minimization of electrostatic

build up contributes towards the reduction in edge release. Alternatively, or in addition, anti-static material may be incorporated onto the lower surface of polyurethane film 30f or into adhesive layer 40f of polyurethane film 30f.

APPLICABILITY TO VARIOUS TYPES OF DEVICES

While the embodiments described above are wound dressings or IV hold down devices, the various aspects of the present invention are also applicable to devices designed to deliver active ingredients to or through the dermal or mucosal layers. Such delivery systems typically deliver the active via a gel modulated system, membrane modulated system, or an adhesive modulated system. All of the embodiments of Figs. 1-13 can be made to be ingredient delivery devices by incorporating an active ingredient into adhesive layer 40-40F, for example.

Other delivery systems are depicted generally in figure 14 and typically include a breathable and waterproof polymeric film 30g. Layered to a first side of film 30g is adhesive layer 40g. Adhered to adhesive layer 40g of film 30g is an active ingredient containing island 60g. Island 60g comprises a thin or ultra thin polymeric backing film 62g. Layered to backing film 62g is an active ingredient layer 63g that may or may not be incorporated into an adhesive.

The foregoing are preferred embodiments of the invention and changes and variations can be made without departing from the spirit and broader aspects of the invention, as defined in the appended claims, which are to be interpreted in accordance with the principles of patent law, including the Doctrine of Equivalents.

CONCLUSION

The embodiments described above minimize the problem of edge release which typically occurs in adhesive devices used as wound dressings, ingredient delivery devices and IV hold downs. Experience has shown that regardless of differences in adhesive strength between the

skin or mucosa contacting adhesive and the handle adhesive, there is a tendency for the edge of the polymeric film to lift away from the user's skin or mucosa when the handle member is peeled away from the back of the polymeric film.

Of course it is understood that the above are preferred embodiments only, and that various changes and alterations can be made without departing from the spirit and scope of the invention as set forth in the appended claims, as interpreted in accordance with the principles of patent law.

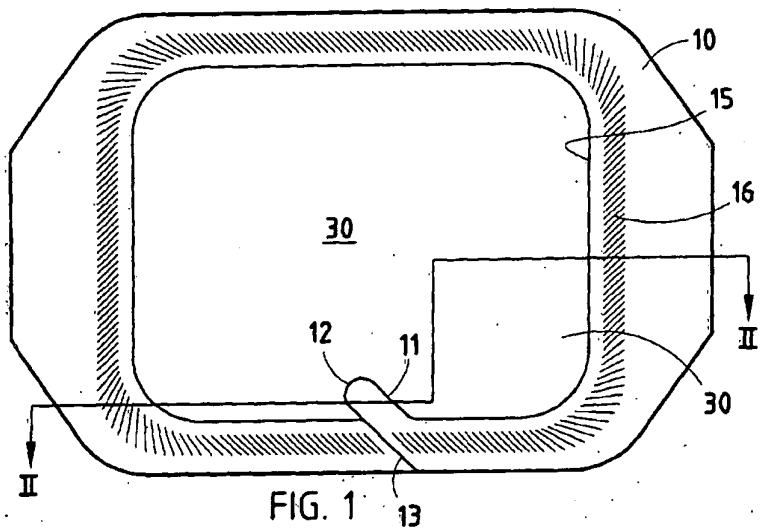


FIG. 1

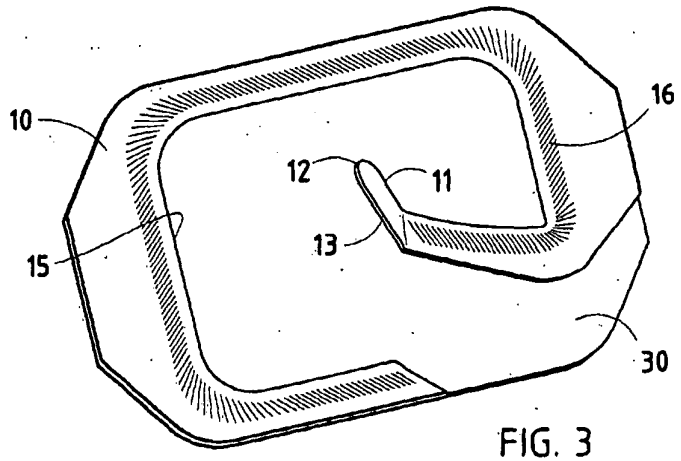


FIG. 3

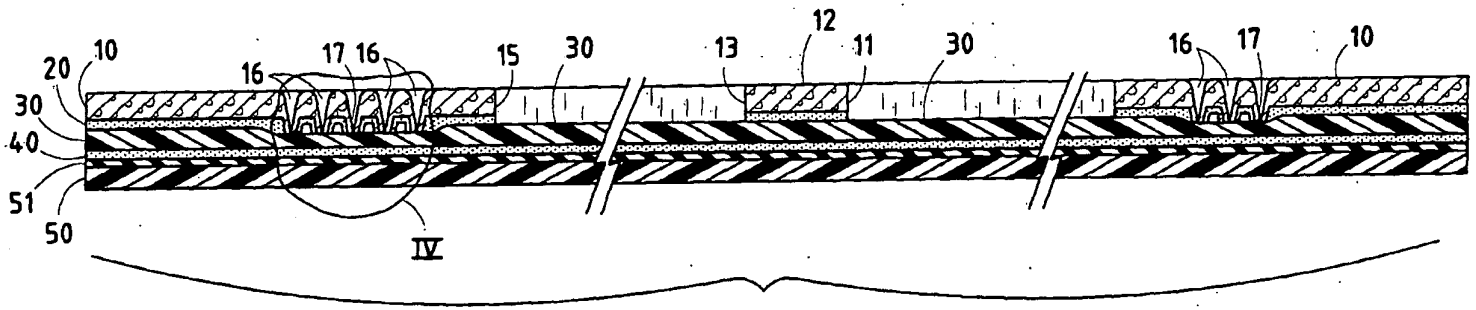


FIG. 2

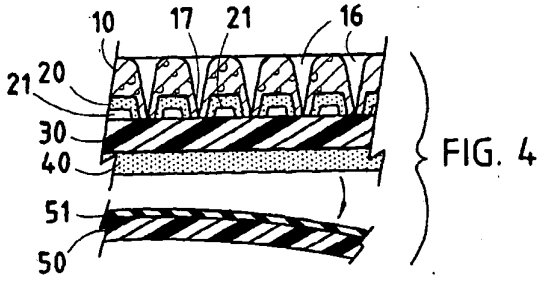


FIG. 4

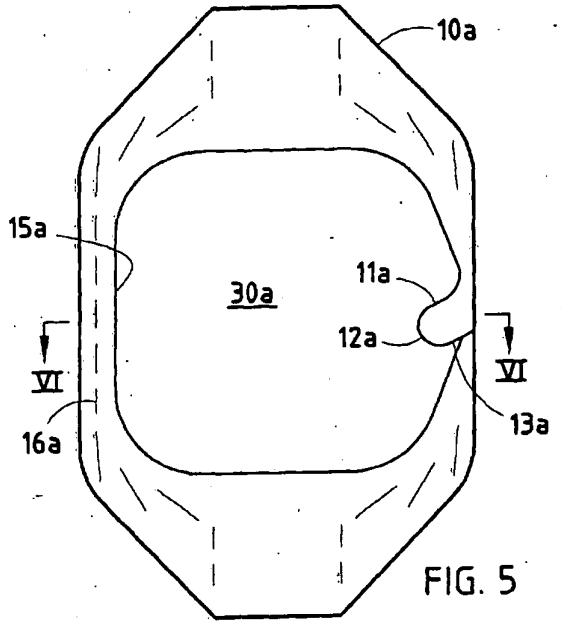


FIG. 5

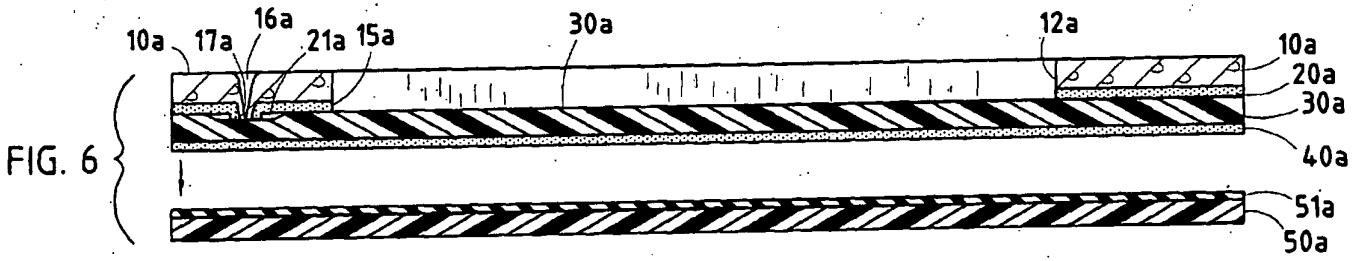


FIG. 6

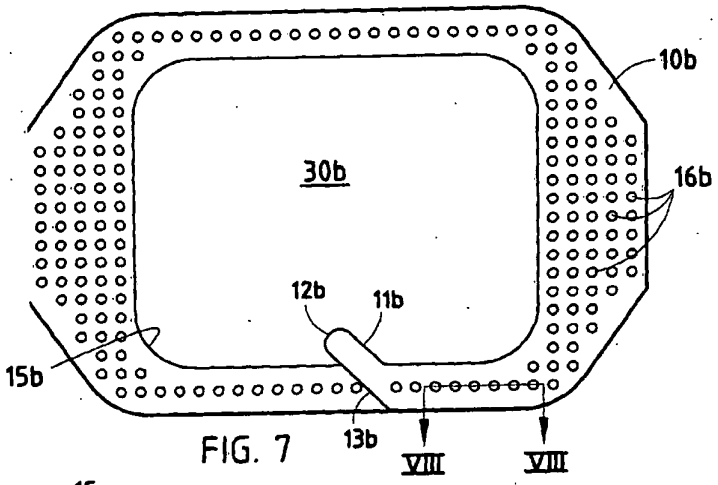


FIG. 7

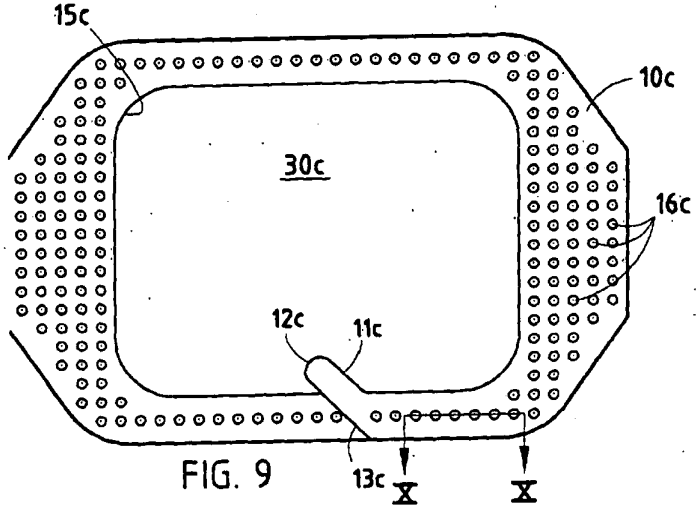


FIG. 9

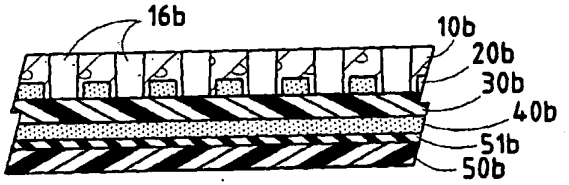


FIG. 8

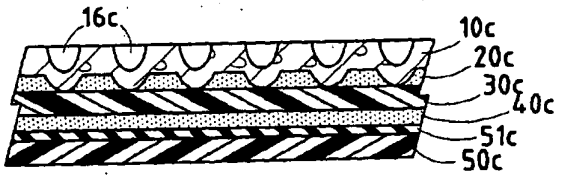


FIG. 10

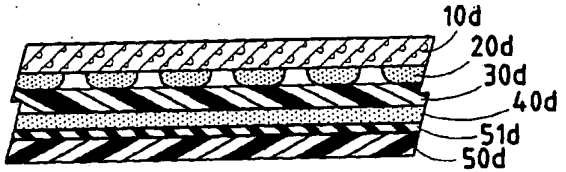


FIG. 11

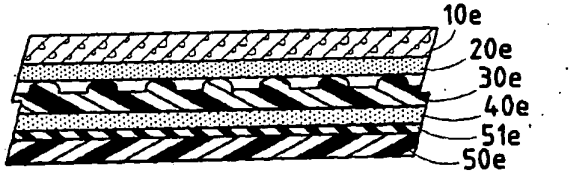


FIG. 12

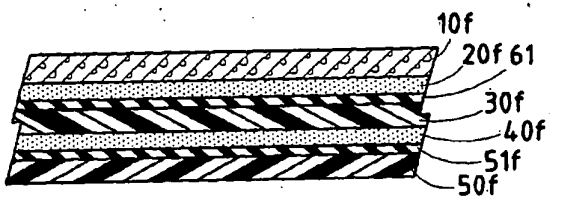
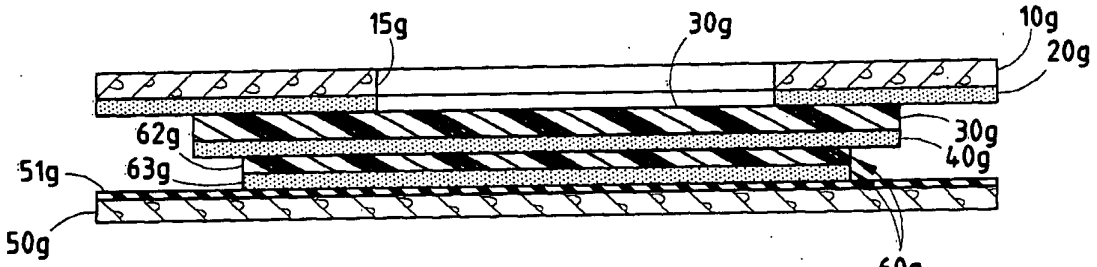


FIG. 13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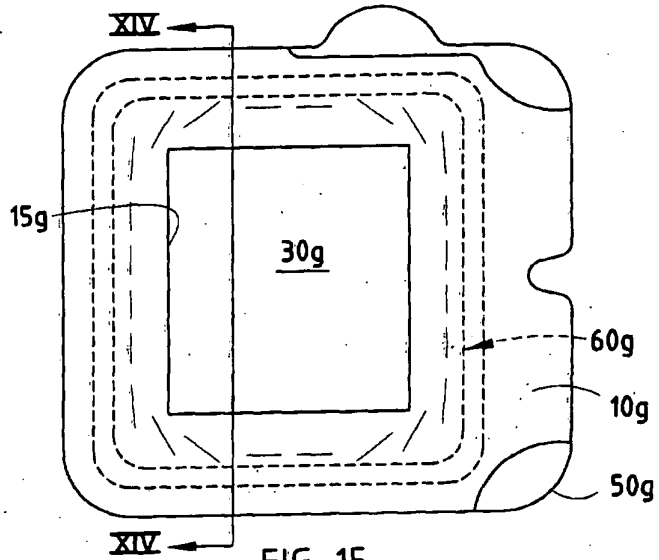
10g
20g
62g
30g
40g
51g
63g
50g
60g

FIG. 14


XIV
15g
30g
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10g
50g
XIV

FIG. 15